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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/470,276 | 12/22/99 | KOLODNER | R 157/47483-C |

HM12/0731

NIXON PEABODY LLP
101 FEDERAL ST
BOSTON MA 02115

| EXAMINER | |
|---|---|
| FREDMAN, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1655 | 6 |

**DATE MAILED:** 07/31/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/470,276 | Kolodner et al |
| **Examiner** | **Group Art Unit** |
| Jeffrey Fredman | 1655 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ___*one*___ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-38* _____ is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Sequence Rules*

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 due to the absence of a CRF for the SEQ ID NOs listed in the paper copy. Please see the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. A complete response to this action will require compliance with the Sequence Rules.

### *Election/Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to the protein, classified in class 530, subclass 350.

II. Claims 2-12, drawn to nucleic acids, classified in class 536, subclass 23.1.

III. Claims 13-37, drawn to nucleic acid detection methods, classified in class 435, subclass 6.

IV. Claim 38, drawn to drug screening methods, classified in class 436, subclass 501.

3. The inventions are distinct, each from the other because of the following reasons:

4. Inventions in Group I and in Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are unrelated because the protein is different functionally, structurally and chemically from the nucleic acids of Group II or the nucleic acid methods of Group III, and has a different mode of operation and different functions and effects

5. Inventions in Group I and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be expressed in cells and used for drug screening, or it can be used for antibody synthesis, for protein purification, or microinjected for biological activity..

6. Inventions in Group II and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid can be used in the detection method of Group III, or in purification methods or in expression methods or in antisense therapy methods or in gene therapy methods.

7. Inventions in Groups II and III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the different inventions are unrelated because the nucleic acid and nucleic acid detection method differ in operation, function and effect from the drug screening method of Group IV.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. These claims are generic to a plurality of disclosed patentably distinct species comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 10 disclosed species representing 10 different SEQ ID NOs even though this requirement is traversed.

This species requirement is based upon the notice in the Official Gazette in October 1996 which states, "Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement. Only the ten (10) nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined."

Should applicant traverse on the ground that some or all of the different nucleic acid species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. A telephone call was made to Ronald Eisenstein on July 27, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Group 1800 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

**Jeffrey Fredman**
**Primary Patent Examiner**
**Art Unit 1655**

July 27, 2000